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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,340	04/21/2005	Terry Beaumont	9052-205	8759
20792 7590 02/05/2007 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER BERHANU, ETSUB D	
			ART UNIT 3768	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS			MAIL DATE 02/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/506,340

Applicant(s)

BEAUMONT, TERRY

Examiner

Etsub D. Berhanu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 1 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarnoff'094 (previously cited).

Sarnoff'094 discloses a sensing device comprising: physiological sensing means comprising pulse oximetry optical transmitters and a receiver, and a temperature sensor in contact with a heat transfer tip (page 7, lines 1-14); locating means to locate the sensing means inside an ear canal, wherein the locating means is provided with an aperture which, when the sensing device is fitted in the ear canal, allows motion of the air in and out of the ear canal (see Figure 3 and page 10, lines 6-22); a generally O-shaped locating means (see Figures 2 and 3); locating means made of pliable material which is adapted to fit comfortably within the ear canal, and wherein the locating means comprises adjusting means such that the device can be comfortably accommodated by a multiplicity of different users (page 9, line 27 – page 10, line 2); locating means made of silicone (page 4, lines 23-26); and an audio communication means wherein the audio communication means comprises a microphone located within a vibration absorbent material, wherein the absorbent material is a thermoplastic elastomer (page 4, line 23 – page 5, line 7).

Regarding the limitation in claim 1 requiring the locating means to have a substantially U-shaped transverse cross section, it is noted that the Applicant has failed to provide criticality for said U-shaped transverse cross section in the Specification. Applicant discloses on page 1 of the Remarks filed 14 November 2006 that the U-shaped cross section of the locating means is merely to allow air to pass in and out of the ear canal. The locating means of Sarnoff'094 having the circular or O-shaped transverse cross section, as pointed out by Applicant on page 2 of the Remarks, provides the same advantage as the

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locating means having the U-shaped transverse cross section of the current application. Therefore, it would have been within the skill of the art to implement the locating means of Sarnoff'094 with a U-shaped transverse cross section since the Applicant has not shown criticality or unexpected results of the U-shaped transverse cross section and absent criticality or unexpected results it has generally been held to be within the skill level of the art to implement a locating element with a variety of shapes capable of securing an apparatus within an ear canal, including one having a U-shaped cross section.

3. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarnoff'094, as applied to claim 1, further in view of Schulze et al.'692 (previously cited).

Sarnoff'094 discloses all of the elements of the current invention, as discussed in paragraph 2, except for the locating means comprising securing means, wherein the securing means comprises an ear clip which partially or completely surrounds the top or bottom of the ear.

Schulze et al.'692 teaches the use of an adjusting and securing means comprising an ear clip which partially or completely surrounds the ear around the top or bottom of the ear in order to secure an optical sensor to an ear (col. 5, lines 49-56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the locating means of Sarnoff'094 to include the securing means of Schulze et al.'692, since it would allow the optical sensors of Sarnoff'094 to be secured to the ear.

4. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarnoff'094, as applied to claim 1, further in view of Raff'931 (previously cited).

Sarnoff'094 discloses all of the elements of the current invention, as discussed in paragraph 2, except for the audio communication means comprising a speaker.

Raff'931 teaches the use of a speaker in an audio communication means in a monitoring ear piece system to orally communicate between a patient and a nursing station (col. 2, lines 33-36).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the audio communication means of Sarnoff'094 to include a speaker, as taught by Raff'931, since it would allow audible communication between a patient and nursing station.

Regarding claim 15, it is noted that while Sarnoff'094 discloses the use of a thermoplastic elastomer or thermoset silicone as material for the earmold locating means, Sarnoff'094 fails to disclose a specific thermoplastic elastomer or thermoset silicone. It would have been within the skill of the art to determine an appropriate thermoplastic elastomer or thermoset silicone including one with a sure hardness between 30 and 60 % in order to assure that the locating means is pliable so as to be adjusted for the use by multiple users, and also comfortable when inserted in a patient's ear canal.

Response to Arguments

5. Applicant's arguments filed 14 November 2006 have been fully considered but they are not persuasive. Applicant argues on page 2 of the Remarks that a U-shaped transverse cross section would be unworkable in the context of the teachings of Sarnoff'094 since it would result in the loss of the gripping effect of the conical fins and could possibly expose the electronics assembly. Examiner notes that even in having a U-shaped transverse cross section, the conical fins would be able to maintain a sufficient gripping effect on 3 sides of the inner ear as it is well known in the art, through due experimentation, to determine the outward exerting forces required to maintain adequate gripping on 3 sides of an object. Regarding Applicant's argument that the electronics assembly might be exposed, Sarnoff'094 discloses that the electronics assembly is placed in a flexible casing (page 3, lines 22-28), thus preventing exposure.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDB

ERIC F. WINAKUR
PRIMARY EXAMINER